

## CON Regulation of Diagnostic Centers

CON regulation of “diagnostic centers” should be eliminated because the rule is poorly defined, often misinterpreted or ignored by providers, and rarely enforced. The following definition is provided in the CON statute:

**§ 131E-176. Definitions.** (7a) *"Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.*

This definition requires non-hospital providers to obtain CON approval if the total cost to acquire diagnostic equipment exceeds \$500,000. The Certificate of Need Section interprets the \$500,000 threshold to be the cumulative cost based on the original equipment purchase price.

Consider the following scenario: A large physician group obtained three radiography units and installed these in their office in 1998 with the total equipment purchase cost of \$375,000 plus the design, installation, inspections and construction cost of \$75,000. This was not subject to CON review because the total capital cost was \$450,000. Now the physician group wants to spend \$400,000 to replace two of these radiography units with digital radiography equipment so that the images can be obtained digitally and transmitted to the hospital or other physician specialists without the use of film. This would cause the cumulative cost of the diagnostic equipment at the physician office to exceed \$500,000 because the original purchase price of the one remaining radiography unit was \$125,000 plus the design and installation costs. Thus, the physicians would be required to obtain CON approval as a diagnostic center.

This aspect of the CON law is often misunderstood because most physicians and practice managers do not recognize that the threshold is based on cumulative costs. Furthermore, the CON law regarding diagnostic centers is deficient because it contains no definition of diagnostic equipment. Therefore many people do not comprehend that the diagnostic center regulations apply to a vast array of equipment including ultrasound equipment in obstetricians' offices, stress test machines in cardiologists' offices, and the many types of ophthalmic and optometric equipment.

Thousands of physician practices in North Carolina have various modalities of diagnostic equipment. There is no single database that reports the inventory all of the various types of equipment. The North Carolina Division of Health Service Regulation Radiation Protection Section regulates X-ray equipment and mammography equipment and it licenses providers with equipment that use radioactive materials. This agency does not regulate many other types of diagnostic equipment that are commonly used in physician offices including ultrasound equipment, EKG machines, holter monitors, stress test machines, pulmonary function systems and ophthalmic / optometry equipment..

Having a \$500,000 threshold for a diagnostic center makes it difficult and burdensome for non-hospital providers to obtain digital radiography, digital mammography equipment, ultrasound

units, and other diagnostic equipment that are not specifically regulated by CON law. A CON application to acquire replacement or additional diagnostic equipment can cost \$20,000 or more to prepare; if it is challenged by the hospital or other providers the legal costs could be hundreds of thousands of dollars. Consequently, the current CON regulation of diagnostic centers discourages physicians and non-hospital providers from replacing outdated equipment with safer, digital equipment that can transmit images and greatly reduce the need for a patient to have repeated diagnostic tests.

Certificate of Need officials do not have the resources to provide comprehensive enforcement of the diagnostic center CON regulations. If the agency receives a complaint or a request for investigation, the CON staff does investigate and send letters to providers requesting information regarding the diagnostic equipment at the specified location. The outcome of these investigations may require the provider to submit a CON application or pay a fine.

If the CON law is changed to eliminate future regulation of diagnostic centers, those facilities that are currently designated by the DHSR, CON Section as diagnostic centers should be granted the option of either maintaining their present status as a “health service facility” or voluntarily relinquishing this status. In this way, the change in the CON law would not cause unintended consequences or hardship for healthcare providers that may be acquired in the future. Another option to minimize unintended consequences would be to add an exemption to the CON law that permits the acquisition of existing diagnostic centers without CON approval.